UNITED STATES PATENT AND TRADEMARK OFFICE

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

PTOL-90A (Rev. 04/07)

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2007*.

2a)☒ This action is **FINAL**.   2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7-10,12-24,39,41-46 and 48-60* is/are pending in the application.

     4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5, 7-10, 12-24, and 39, 41-46,48-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

     a)☐ All   b)☐ Some * c)☐ None of:

         1.☐ Certified copies of the priority documents have been received.

         2.☐ Certified copies of the priority documents have been received in Application No. _____.

         3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

     * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1.   This communication is in response to the amendment filed 8/9/06. Claims 1, 3-5,

7-10, 12-24, and 39, 41-46,48-60 are pending.

Claim Rejections - 35 USC § 103

2.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set
> forth in section 102 of this title, if the differences between the subject matter sought to be patented and
> the prior art are such that the subject matter as a whole would have been obvious at the time the
> invention was made to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was made.

3.   Claims 1, 3-5, 7-10, 12-14, 17-24,39,41-43,46,48-50,53-57, and 60 are rejected

under 35 U.S.C. 103(a) as being unpatentable over Knight (USPAP 2002/0099570) in

view of Schmidt. (USPN 6,839,678) and in further view of McAlindon (US 7,251,609)

[claim 1] Knight discloses a method for matching patients with clinical trials, comprising:

-    receiving patient profile information for a patient at a server connected to a computer

     network, the patient profile information submitted by a user at a terminal connected

     to the network; (par. 68)

-    comparing the patient profile information with acceptance criteria for clinical trials

     stored in a database, the comparison performed by the server; and (par. 63,69))

- automatically, determining whether the patient prequalified for any of the clinical

  trials based on the comparison of the patient profile information with the acceptance

  criteria; and (par. 63)

- if the patient prequalified, for any of the clinical trials notifying the user that the

  patient has prequalified for at least one specific clinical trial; (par. 73—trial contact

  information appears)

- presenting to the user a series of questions targeted to the at least one specific

  clinical trial after determining that the patient prequalifies for any of the clinical trials;

  (par. 70)

- determining whether the user prequalifies for at least one specific clinical trial based

  on the users response to the targeted questions; and (par. 70)

- storing the responses to the targeted questions. (par. 70-73)

Claim 1 has been amended to recite that if the user prequalifies for at least one

specific clinical trial, the user is provided with an application for participation in the

specific drug trial. Knight discloses a system/method which presents a series of

targeted to the at least one specific clinical trial after determining that the patient

prequalifies for any of the clinical trials (par. 70).

However, Knight does not expressly disclose providing the user with an

application to apply/ consent for participation in the specific clinical trial. Schmidt

discloses a system/method wherein the prequalified patient is sent an application for the

clinical trial in question after it is determined that he/she is qualified for the study. (Col.

4, lines 64-col. 5, line 9) The patient is provided documents including Declaration to

Consent, which must be affirmed before they are enrolled in the study. At the time of

the Applicant's invention, it would have been obvious to one of ordinary skill in the art to

modify the method of Knight the teachings Schmidt to provide a study specific

application to the patient (e.g. consent/enrollment form) to the patient once they have

prequalified for at least one study. As suggested by Schmidt, one would have been

motivated to include this feature to provide a simpler and more effective manner of

completing medical studies, which allows sufficient numbers of patients for medical

studies to be obtained more quickly. (col. 1, lines 65-67; col. 2, lines 13-19)

Claim 1 has been further amended to recite:

- if the user prequalifies for the at least one specific clinical trial, providing
  the user with an application to for the user to request to be a participant in
  the specific clinical trial at a clinical trial site for the specific clinical trial;

- and if the user's application is accepted by a clinical trial site for the
  specific clinical trial, prov!ding the contact information for the clinical trial
  site.

Knight and Schmidt do not expressly disclose:

if the user prequalifies for the at least one specific clinical trial, providing the user

with an application to for the user to request to be a participant in the specific clinical

trial at a clinical trial site for the specific clinical trial; and if the user's application is

accepted by a clinical trial site for the specific clinical trial, prov!ding the contact

information for the clinical trial site.

McAlindon discloses a method wherein if the user prequalifies for the at least

one specific clinical trial, providing the user with an application to for the user to request

to be a participant in the specific clinical trial at a clinical trial site for the specific clinical

trial; and if the user's application is accepted by a clinical trial site for the specific clinical

trial, prov!ding the contact information for the clinical trial site. (Figure 2, 6; col. 6, lines

5-60) At the time of the applicant's invention, it would have been obvious to one of

ordinary skill in the art to modify the method of Knight and Schmidt in combination with

the teaching of McAlindon with the motivation of minimizing the time burdens delays

associated with gathering participants and observations for clinical studies. (See

McAlindon: col. 1, lines 51-col. 2, line 60)

[claim 3] Knight teaches a method further including providing the user with instructions

for enrolling in the clinical trial for which the user has prequalified. (par. 73—the user is

sent contact information if he/she qualifies)

[claim 4] Knight teaches a method further including asking the user a plurality of

questions and creating a patient profile based on the responses to the plurality of

questions. (figure 1; par. 68—e.g. gathering demographic data)

[claim 5] Knight teaches a method of claim 4, wherein the step of asking the user a

plurality of questions includes: asking the user one or more static questions; asking the

user one or more dynamic questions which are selected based on the user's responses

to other static and dynamic questions; and creating a the patient profile based on the

responses to the static and dynamic questions. (Figures 1, par. 68, 72-75)

[claim 7] Knight teaches a method of wherein static questions, dynamic questions, and

targeted questions are provided with a plurality of answer options, and the user may

select one or more answer options in order to answer the questions. (Figure 3-6; par.

75-77)

[claim 8] Knight teaches a method of claim 7, wherein the user is required to submit an

answer in a specified format, the specified format being suitable for evaluation by a

computer program process. (par. 57: e.g. web-based interface)

[claim 9] Knight teaches a method further including updating the static questions,

dynamic questions, or answer options. (par. 84-85)

[claim 10] Knight teaches a method wherein the network is the Internet. (par. 57: e.g.

web-based interface; par.75—web pages presented)

[claims 12-13] Knight teaches a method wherein the user answers several steps of

questions on-line. Knight further discloses that information is submitted by the user on-

line and that this data is stored on a server. (Figures 29-30) However, Knight does not

expressly disclose providing the user with an application to apply/ consent for

participation in the specific clinical trial. Schmidt discloses a system/method wherein

the prequalified patient is sent an application/consent form for the clinical trial in

question, wherein the patient fills out the application/consent online and, wherein the

application is sent to a clinical trial site. (Col. 4, lines 64-col. 5, line 15) The patient is

provided documents including Declaration to Consent, which must be affirmed before

they are enrolled in the study. At the time of the Applicant's invention, it would have

been obvious to one of ordinary skill in the art to modify the method of Knight the

teachings Schmidt to have the patient fill-out an online application (e.g.

consent/enrollment form) and to forward this form to the clinical site. As suggested by

Schmidt, one would have been motivated to include this feature to provide a simpler

and more effective manner of completing medical studies, which allows sufficient

numbers of patients for medical studies to be obtained more quickly. (col. 1, lines 65-67;

col. 2, lines 13-19)

[claim 14] Knight teaches a method wherein the patient profile is forwarded to clinical

trial site (par. 109,125,), but does not expressly disclose that the profile information is

sent with the application/consent form. Schmidt discloses a method wherein the patient

profile is sent with the application/consent form to the clinical trial site. (col. 5, lines 6-

22) At the time of the Applicant's invention, it would have been obvious to one of

ordinary skill in the art to modify the method of Knight the teachings Schmidt to have the

patient online application (e.g. consent/enrollment form) and patient profile forwarded to

the clinical site. As suggested by Schmidt, one would have been motivated to include

this feature to provide a simpler and more effective manner of completing medical

studies, by facilitating patient data validation. (col. 1, lines 65-67; col. 2, lines 27-34)

[claim 17] Knight discloses a method wherein the user is provided with a search engine

that allows the user to search for medical information before selecting a clinical trial.

(par. 65-68)

[claim 18] Knight teaches a method wherein the acceptance/matching criteria include

geographic location. (par. 76/Fig. 4—geographic location and preferences are match

criteria)

[claim 19]   Knight discloses a system for matching patients with clinical trials,

comprising:

- a server connected to a network;(Figure 29)

- a data storage device included in the server, and (Figure 29)

- a database located in the data storage device, the database storing patient profile

    information for a patient and acceptance criteria for a plurality of clinical trials;

    (Figures 29-30, par. 68)

- the server comparing the patient profile information with the acceptance criteria for

  the clinical trials stored in the database, (par. 63,69)

- automatically, determining whether the patient prequalifies for any of the clinical

  trials based on the comparison of the patient profile information with the acceptance

  criteria; and (par. 63)

- if the patient preaqualifies for any of the clinical trials, notifying the user that the

  patient has prequalified for at least one specific clinical trial; (par. 73—trial contact

  information appears)

- presenting to the user a series of questions targeted to the at least one specific

  clinical trial after determining that the patient prequalifies for any of the clinical trials;

  (par. 70)

- determining whether the user prequalifies for the at least cone specific clinical trial

  based on the user's response to the targeted questions: and (par. 70)

- storing the responses to the targeted questions (par. 70-73)

   Claim 19 has been amended to recite that if the user prequalifies for at least one

specific clinical trial, the user is provided with an application for participation in the

specific drug trial. Knight discloses a system/method which presents a series of

targeted to the at least one specific clinical trial after determining that the patient

prequalifies for any of the clinical trials (par. 70).

   However, Knight does not expressly disclose providing the user with an application

to apply/ consent for participation in the specific clinical trial. Schmidt discloses a

system/method wherein the pre-qualified patient is sent an application for the clinical

trial in question after it is determined that he/she is qualified for the study. (Col. 4, lines 64-col. 5, line 9) The patient is provided documents including Declaration to Consent, which must be affirmed before they are enrolled in the study. At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system of Knight the teachings Schmidt to provide a study specific application to the patient (e.g. consent/enrollment form) to the patient once they have pre-qualified for at least one study. As suggested by Schmidt, one would have been motivated to include this feature to provide a simpler and more effective manner of completing medical studies, which allows sufficient numbers of patients for medical studies to be obtained more quickly. (col. 1, lines 65-67; col. 2, lines 13-19)

Claim 19 has been further amended to recite:

- if the user prequalifies for the at least one specific clinical trial, providing the user with an application to for the user to request to be a participant in the specific clinical trial at a clinical trial site for the specific clinical trial;

- and if the user's application is accepted by a clinical trial site for the specific clinical trial, prov!ding the contact information for the clinical trial site.

Knight and Schmidt do not expressly disclose:

if the user prequalifies for the at least one specific clinical trial, providing the user with an application to for the user to request to be a participant in the specific clinical trial at a clinical trial site for the specific clinical trial; and if the user's application is

accepted by a clinical trial site for the specific clinical trial, prov!ding the contact

information for the clinical trial site.

McAlindon discloses a method wherein if the user prequalifies for the at least

one specific clinical trial, providing the user with an application to for the user to request

to be a participant in the specific clinical trial at a clinical trial site for the specific clinical

trial; and if the user's application is accepted by a clinical trial site for the specific clinical

trial, prov!ding the contact information for the clinical trial site. (Figure 2, 6; col. 6, lines

5-60) At the time of the applicant's invention, it would have been obvious to one of

ordinary skill in the art to modify the method of Knight and Schmidt in combination with

the teaching of McAlindon with the motivation of minimizing the time burdens delays

associated with gathering participants and observations for clinical studies. (See

McAlindon: col. 1, lines 51-col. 2, line 60)

[claim 20] Knight teaches a system wherein the database contains information on

disease records; drug records; clinical trial records; and patient profile records. (par. 66;

75-77)

[claim 21] Knight teaches a system wherein a record in the database contains links to

other related records. (Fig. 30)

[claim 22] Knight teaches a system wherein the server transmits a plurality of questions

to the user over the network, the server also transmits a plurality of answer choices for

each question, the server receives responses from the user, and the server builds a

patient profile based on the responses. (Figures 1, par. 68, 72-75)

[claim 23] Knight teaches a system wherein the server retrieves a disease/subdisease record corresponding to a disease/sub-disease entered by the user, the disease/-sub-disease record containing links to question records, the server retrieving the question records to access questions to be provided to the user. (Figures 1-2; par. 72)

[Claim 24, 54] The limitations of claim 24 and 54 recite a computer executable software instructions for causing a computer to perform the method recited in claim 1. Insofar as the method of claim 1 has been shown to be fully disclosed and computer implemented by the teachings of Knight in view of Schmidt in the rejection of claim 1, it is submitted that claims 24 and 54 are rejected for the same reasons provided in the rejection of claim 1, and incorporated herein.

[claim 39]   Knight teaching method comprising the steps of:

- presenting at least one web page to permit an individual to be registered with a database by submitting information indicating whether notice of one or more clinical studies is desired and registration information, wherein the registration information includes at least a geographic location, a disease condition of interest, and contact Information; (par. 55, par. 128-131)

- automatically registering the individual with the database upon receipt of the registration and indicating information; (par. 131)

- automatically determining, in accordance with the indicating information and the registration information whether to provide notice of a clinical study related to said disease condition; (par. 133)

- providing notice of said clinical study; (par. 133)

- presenting a screening questionnaire associated with said clinical study; and (Figure 10)

- storing in the database answers submitted in response to said questionnaire. (par. 80)

Claim 39 has been amended to recite that based upon responses to the screening questionnaire, the user is provided with an application for participation in the specific clinical trial. Knight discloses a system/method which presents a series of targeted to the at least one specific clinical trial after determining that the patient prequalifies for any of the clinical trials (par. 70).

However, Knight does not expressly disclose providing the user with an application to apply/ consent for participation in the specific clinical trial. Schmidt discloses a system/method wherein the pre-qualified patient is sent an application for the clinical trial in question after it is determined that he/she is qualified for the study. (Col. 4, lines 64-col. 5, line 9) The patient is provided documents including Declaration to Consent, which must be affirmed before they are enrolled in the study. At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system of Knight the teachings Schmidt to provide a study specific application to the patient (e.g. consent/enrollment form) to the patient once they have

pre-qualified for at least one study. As suggested by Schmidt, one would have been
motivated to include this feature to provide a simpler and more effective manner of
completing medical studies, which allows sufficient numbers of patients for medical
studies to be obtained more quickly. (col. 1, lines 65-67; col. 2, lines 13-19)

Claim 39 has been further amended to recite:

- if the user prequalifies for the at least one specific clinical trial, providing
  the user with an application to for the user to request to be a participant in
  the specific clinical trial at a clinical trial site for the specific clinical trial;

- and if the user's application is accepted by a clinical trial site for the
  specific clinical trial, prov!ding the contact information for the clinical trial
  site.

Knight and Schmidt do not expressly disclose:

if the user prequalifies for the at least one specific clinical trial, providing the user
with an application to for the user to request to be a participant in the specific clinical
trial at a clinical trial site for the specific clinical trial; and if the user's application is
accepted by a clinical trial site for the specific clinical trial, prov!ding the contact
information for the clinical trial site.

McAlindon discloses a method wherein if the user prequalifies for the at least
one specific clinical trial, providing the user with an application to for the user to request
to be a participant in the specific clinical trial at a clinical trial site for the specific clinical
trial; and if the user's application is accepted by a clinical trial site for the specific clinical

trial, prov!ding the contact information for the clinical trial site. (Figure 2, 6; col. 6, lines 5-60) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Knight and Schmidt in combination with the teaching of McAlindon with the motivation of minimizing the time burdens delays associated with gathering participants and observations for clinical studies. (See McAlindon: col. 1, lines 51-col. 2, line 60)

[claims 41-42] Knight teaches a method wherein the user answers several steps of questions on-line. Knight further discloses that information is submitted by the user on-line and that this data is stored on a server. (Figures 29-30) However, Knight does not expressly disclose providing the user with an application to apply/ consent for participation in the specific clinical trial. Schmidt discloses a system/method wherein the prequalified patient is sent an application/consent form for the clinical trial in question, wherein the patient fills out the application/consent online and, wherein the application is sent to a clinical trial site. (Col. 4, lines 64-col. 5, line 15) The patient is provided documents including Declaration to Consent, which must be affirmed before they are enrolled in the study. At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Knight the teachings Schmidt to have the patient fill-out an online application (e.g. consent/enrollment form) and to forward this form to the clinical site. As suggested by Schmidt, one would have been motivated to include this feature to provide a simpler and more effective manner of completing medical studies, which allows sufficient

numbers of patients for medical studies to be obtained more quickly. (col. 1, lines 65-67;

col. 2, lines 13-19)

[claim 43] Knight teaches a method wherein the patient profile is forwarded to clinical

trial site (par. 109,125,), but does not expressly disclose that the profile information is

sent with the application/consent form. Schmidt discloses a method wherein the patient

profile is sent with the application/consent form to the clinical trial site. (col. 5, lines 6-

22) At the time of the Applicant's invention, it would have been obvious to one of

ordinary skill in the art to modify the method of Knight the teachings Schmidt to have the

patient online application (e.g. consent/enrollment form) and patient profile forwarded to

the clinical site. As suggested by Schmidt, one would have been motivated to include

this feature to provide a simpler and more effective manner of completing medical

studies, by facilitating patient data validation. (col. 1, lines 65-67; col. 2, lines 27-34)

[claim 46] Knight further discloses a wherein the user is provided with a search engine

that allows the user to search for medical information before selecting a clinical study.

(par. 65-68)

 [claims 48-49]   Knight teaches a system wherein the user answers several steps

of questions on-line. Knight further discloses that information is submitted by the user

on-line and that this data is stored on a server. (Figures 29-30) However, Knight does

not expressly disclose providing the user with an application to apply/ consent for

participation in the specific clinical trial. Schmidt discloses a system/method wherein

the pre-qualified patient is sent an application/consent form for the clinical trial in

question, wherein the patient fills out the application/consent online and, wherein the

application is sent to a clinical trial site. (Col. 4, lines 64-col. 5, line 15) The patient is

provided documents including Declaration to Consent, which must be affirmed before

they are enrolled in the study. At the time of the Applicant's invention, it would have

been obvious to one of ordinary skill in the art to modify the method of Knight the

teachings Schmidt to have the patient fill-out an online application (e.g.

consent/enrollment form) and to forward this form to the clinical site. As suggested by

Schmidt, one would have been motivated to include this feature to provide a simpler

and more effective manner of completing medical studies, which allows sufficient

numbers of patients for medical studies to be obtained more quickly. (col. 1, lines 65-67;

col. 2, lines 13-19)

[claim 50] Knight teaches a method wherein the patient profile is forwarded to clinical

trial site (par. 109,125,), but does not expressly disclose that the profile information is

sent with the application/consent form. Schmidt discloses a method wherein the patient

profile is sent with the application/consent form to the clinical trial site. (col. 5, lines 6-

22) At the time of the Applicant's invention, it would have been obvious to one of

ordinary skill in the art to modify the method of Knight the teachings Schmidt to have the

patient online application (e.g. consent/enrollment form) and patient profile forwarded to

the clinical site. As suggested by Schmidt, one would have been motivated to include

this feature to provide a simpler and more effective manner of completing medical

studies, by facilitating patient data validation. (col. 1, lines 65-67; col. 2, lines 27-34)

[claim 53] Knight further discloses a system claim 19, wherein the user is provided with

a search engine (i.e. that allows the user to search for medical information before

selecting a clinical study.) (par. 65-68)

[claims 55-56] Knight and Schmidt disclose a computer executable software code of

claim 24 as explained in the rejection of claim 24.

        Knight teaches a method wherein the user answers several steps of questions

on-line. Knight further discloses that information is submitted by the user on-line and

that this data is stored on a server. (Figures 29-30) However, Knight does not expressly

disclose providing the user with an application to apply/ consent for participation in the

specific clinical trial. Schmidt discloses a system/method wherein the prequalified

patient is sent an application/consent form for the clinical trial in question, wherein the

patient fills out the application/consent online and, wherein the application is sent to a

clinical trial site. (Col. 4, lines 64-col. 5, line 15) The patient is provided documents

including Declaration to Consent, which must be affirmed before they are enrolled in the

study. At the time of the Applicant's invention, it would have been obvious to one of

ordinary skill in the art to modify the method of Knight the teachings Schmidt to have the

patient fill-out an online application (e.g. consent/enrollment form) and to forward this

form to the clinical site. As suggested by Schmidt, one would have been motivated to

include this feature to provide a simpler and more effective manner of completing

medical studies, which allows sufficient numbers of patients for medical studies to be

obtained more quickly. (col. 1, lines 65-67; col. 2, lines 13-19)

[claim 57] Knight and Schmidt disclose a computer executable software code of claim 24

as explained in the rejection of claim 24.

Knight teaches a method wherein the patient profile is forwarded to clinical trial

site (par. 109,125,), but does not expressly disclose that the profile information is sent

with the application/consent form. Schmidt discloses a method wherein the patient

profile is sent with the application/consent form to the clinical trial site. (col. 5, lines 6-

22) At the time of the Applicant's invention, it would have been obvious to one of

ordinary skill in the art to modify the method of Knight the teachings Schmidt to have the

patient online application (e.g. consent/enrollment form) and patient profile forwarded to

the clinical site. As suggested by Schmidt, one would have been motivated to include

this feature to provide a simpler and more effective manner of completing medical

studies, by facilitating patient data validation. (col. 1, lines 65-67; col. 2, lines 27-34)

[claim 60]   Knight and Schmidt disclose a computer executable software code of

claim 24 as explained in the rejection of claim 24.

Furthermore Knight discloses a method wherein the user is provided with a search engine that allows the user to search for medical information before selecting a clinical study. (par. 65-68)

4.   Claims 15-16, 44-45,51-52, and 58-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knight,Schmidt, and McAlindon as applied to claims 1, 19, 24, and 39 and in further view of Kraftson et al (USPN 6,151,581).

[claim 15]   Knight discloses a method wherein non-identifying patient information maybe forwarded to the trial site (par. 82) and also discloses that the system is designed to protect patient sensitive patient data (par. 125). However, Knight does not expressly disclose that the patient record and application include a patient ID to conceal the patient's identity. Kraftson teaches a system/method wherein a random ID number is assigned to a patient's profile and questionnaire to conceal/protect the patient's identity. (col. 12, lines 53-62) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Knight with the teaching of Kraftson and Schmidt to store the patient's information with a patient ID number. As suggested by Kraftson, one would have been motivated to include this feature to ensure that the patient is free to answer questions honestly and accurately with fear that his/her information will be divulged. (col. 12, lines 35-49)

[claim 16]   Knight teaches a method/ system further including notifying the clinical trial

sponsor when the user submits patient information/registration information to the clinical

trial site. (par. 131 e.g. sharing data with pharmaceutical companies) However, Knight

does not expressly disclose that the sponsor is notified when the patient enrolls/

consents to participation in the study. Schmidt discloses a system and method in which

patient data are made available and the patient is assigned to an appropriate group

when they have consented to participate in the study. (i.e. notification). At the time of

the Applicant's invention, it would have been obvious to one of ordinary skill in the art to

modify the method/system of Knight with the teaching of Schmidt to notify clinical trial

sponsors when users have submitted an application/enrolled in the study. As

suggested by Schmidt, one would have been motivated to include this feature to ensure

that unnecessary data is not provided from a patient who is not qualified or willing to

participate in the study. (col. 5, lines 11-15)

[claim 44] Knight discloses method a wherein non-identifying patient information maybe

forwarded to the trial site (par. 82) and also discloses that the system is designed to

protect patient sensitive patient data (par. 125). However, Knight does not expressly

disclose that the patient registration information and application include a patient ID to

conceal the patient's identity. Kraftson teaches a system/method wherein a random ID

number is assigned to a patient's profile and questionnaire to conceal/protect the

patient's identity. (col. 12, lines 53-62) At the time of the Applicant's invention, it would

have been obvious to one of ordinary skill in the art to modify the method of Knight and

Schmidt with the teaching of Kraftson to store the patient's information with a patient ID

number. As suggested by Kraftson, one would have been motivated to include this

feature to ensure that the patient is free to answer questions honestly and accurately

with fear that his/her information will be divulged. (col. 12, lines 35-49)

[claim 45] Knight teaches a method further including notifying the clinical study sponsor

when the user submits patient information/registration information to the clinical study site.

(par. 131). However, Knight does not expressly disclose that the sponsor is notified

when the patient enrolls/ consents to participation in the study. Schmidt discloses a

system and method in which patient data are made available and the patient is

assigned to an appropriate group when they have consented to participate in the study.

(i.e. notification). At the time of the Applicant's invention, it would have been obvious to

one of ordinary skill in the art to modify the method/system of Knight with the teaching of

Schmidt to notify clinical trial sponsors when users have submitted an

application/enrolled in the study. As suggested by Schmidt, one would have been

motivated to include this feature to ensure that unnecessary data is not provided from a

patient who is not qualified or willing to participate in the study. (col. 5, lines 11-15)

[claim 51] Knight discloses system a wherein non-identifying patient information maybe

forwarded to the trial site (par. 82) and also discloses that the system is designed to

protect patient sensitive patient data (par. 125). However, Knight and Schmidt do not

expressly disclose that the patient registration information and application include a

patient ID to conceal the patient's identity. Kraftson teaches a system/method wherein a random ID number is assigned to a patient's profile and questionnaire to conceal/protect the patient's identity. (col. 12, lines 53-62) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system of Knight and Schmidt in combination with the teaching of Kraftson to store the patient's information with a patient ID number. As suggested by Kraftson, one would have been motivated to include this feature to ensure that the patient is free to answer questions honestly and accurately with fear that his/her information will be divulged. (col. 12, lines 35-49)

[claim 52] Knight discloses a server notifying the clinical study sponsor when the user submits patient information/registration information to the clinical study site. (par. 131). However, Knight does not expressly disclose that the sponsor is notified when the patient enrolls/ consents to participation in the study. Schmidt discloses a system and method in which patient data are made available and the patient is assigned to an appropriate group when they have consented to participate in the study. (i.e. notification). At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method/system of Knight with the teaching of Schmidt to notify clinical trial sponsors when users have submitted an application/enrolled in the study. As suggested by Schmidt, one would have been motivated to include this feature to ensure that unnecessary data is not provided from a patient who is not qualified or willing to participate in the study. (col. 5, lines 11-15)

[claim 58]   Knight and Schmidt teach a computer readable medium with executable

code as explained in the rejection of claim 24.

Furthermore, Knight discloses method a wherein non-identifying patient

information maybe forwarded to the trial site (par. 82) and also discloses that the

system is designed to protect patient sensitive patient data (par. 125). However, Knight

does not expressly disclose that the patient registration information and application

include a patient ID to conceal the patient's identity. Kraftson teaches a system/method

wherein a random ID number is assigned to a patient's profile and questionnaire to

conceal/protect the patient's identity. (col. 12, lines 53-62) At the time of the

Applicant's invention, it would have been obvious to one of ordinary skill in the art to

modify the method of Knight and Schmidt with the teaching of Kraftson to store the

patient's information with a patient ID number. As suggested by Kraftson, one would

have been motivated to include this feature to ensure that the patient is free to answer

questions honestly and accurately with fear that his/her information will be divulged.

(col. 12, lines 35-49)

[claim 59]   Knight and Schmidt teach a computer readable medium with executable

code as explained in the rejection of claim 24.

Furthermore, Knight discloses a method further including a server notifying the

clinical study sponsor when the user submits patient information/registration information

to the clinical study site. (par. 131) However, Knight does not expressly disclose that

the sponsor is notified when the patient enrolls/ consents to participation in the study.

Schmidt discloses a system and method in which patient data are made available and

the patient is assigned to an appropriate group when they have consented to participate

in the study. (i.e. notification). At the time of the Applicant's invention, it would have

been obvious to one of ordinary skill in the art to modify the method/system of Knight

with the teaching of Schmidt to notify clinical trial sponsors when users have submitted

an application/enrolled in the study. As suggested by Schmidt, one would have been

motivated to include this feature to ensure that unnecessary data is not provided from a

patient who is not qualified or willing to participate in the study. (col. 5, lines 11-15)

Response to Arguments

5.   Applicant's arguments with respect to claims 1,19,24, and 39 have been

considered but are moot in view of the new ground(s) of rejection.

Conclusion

6.   **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time

policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Rachel L. Porter whose telephone number is (571) 272-

6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

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system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. L. P./

Examiner, Art Unit 3626

/Joseph Thomas/

Supervisory Patent Examiner, Art Unit 3626